5, line 35; page 14, line 29; page 17, line 11) instead of "extrusion." The Examiner has also objected to the replacement of "extrusion" with "processing."

While Applicant has accommodated the Examiner by removing the term "axially" in the locations designated in the specification, Applicant respectfully disagrees that the introduction of such term constitutes new matter. For instance, FIG. 4 clearly shows the "axial" progression of the blank 7 through the heating stages 9 and 10 and then the forming stage 11. The blank clearly proceeds along its axis and the axis of the equipment. FIG. 5 also clearly shows the "axial" application of the punch 12 with respect to the blank 7. The use of the term "extrusion" in the original specification provides even further support for the introduction of the term "axial" in connection with "pressing." The term extrusion is defined generally as the act or process of pushing or forcing. In FIGS. 4-6, the blank 7 is clearly being pushed and formed or pressed into a mold along the axial direction. Thus, Applicant's introduction of the term "axially pressing" as a means of describing the processing of the blank into shape does not appear to be the introduction of new matter, particularly in view of FIGS. 4-6 that clearly demonstrate the pressing of the blank along the axial direction. It is not critical that the specific terms used in the claims be located verbatim in the specification, as long as the specification and drawings provide support for such terms. In this case, the specification and drawings clearly provide support for the terms "axially pressing" as used in connection with the forming process described and shown. In any event, Applicant has removed the language from the specification and has reworded the claims accordingly.

Applicant has also removed the broader concept of "processing" and replaced the same with "extrusion."

Accordingly, it is respectfully requested that the Examiner withdraw the new matter rejection with respect to the disclosure and with respect to claims 1 and 2 under 35 U.S.C. §112, first paragraph in his Office Action dated December 15, 2000.

Claim 4 is rejected under 35 U.S.C. §112, second paragraph, as failing to particularly point and distinctly claim the subject matter of the invention. Responsive thereto, Applicant has amended claim 4 by deleting "are used" after component. Accordingly, it is respectfully requested that the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph from his Office Action dated December 15, 2000.

Claims 1-15 are rejected under 35 U.S.C. §102(b) and/or §103(a) in view of Gapp et al. (WO 91/02906), while claim 16 is rejected under §103(a) as being unpatentable over Gapp et al. in view of DE 37 39 582. Responsive thereto, Applicant has amended the claims to more particularly define the present invention and to clearly distinguish the present invention from the Gapp et al. reference.

Gapp et al. achieves localized deformation of the head and the threads by heating and deforming the head and the threads separately, while keeping the shank cool. This results in small degrees of deformation along localized areas of the Gapp et al. fastener. The deformation of the Gapp et al. fastener therefore requires at least two heating stages and at least two forming stages, one to affect each end of the fastener.

On the contrary, the process of the present invention achieves a deformation along the entire blank (see, in particular, FIG. 4 and the discussion related thereto) by heating

the entire blank in a heating stage and causing said heated blank to flow in its entirety into the negative mold. The fibers that form the blank, which are distributed over the entire cross-section of the blank, are oriented and distributed in a manner that can be controlled, in very targeted manner, by means of the flowing process. The fiber orientation and fiber distribution and therefore the mechanical properties of a component manufactured according to the process of the present invention, can therefore be specifically characterized and brought into relation with the process parameters of the manufacturing process. By means of pressing of the blank into the negative mold, the fiber orientation can be additionally controlled, so that different strength values can also be achieved over the length of a corresponding component.

The claims have been amended to more particularly define the process of forming a manufacturing component, which process is clearly distinguished from that taught by Gapp et al. Thus, it is respectfully submitted that Gapp et al., alone or in combination with DE '582 reference, fails to teach or reasonably suggest a process for manufacturing components made of fiber-reinforced thermoplastic materials, where a blank formed of fibers and a thermoplastic material is first pre-finished, and said blank is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process, said process comprising the steps of heating the entire blank to a forming temperature in a heating stage, pressing said heated blank into the negative mold and, shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into the negative mold.

Accordingly, it is respectfully requested that the Examiner withdraw the rejections under §102(b) and §103(a) from his Office Action dated December 15, 2000.

In view of the above amendments and remarks, it is believed that claims 1-16, consisting of independent claims 1 and 2 and the claims dependent therefrom, are in condition for allowance. Passage of this case to allowance is earnestly solicited.

Any fee due with this paper, not fully covered by an enclosed check, may be charged on Deposit Account 08-1634.

Respectfully submitted,

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IN THE SPECIFICATION

Please amend the last paragraph on page 5 as follows:

In the process according to the invention, it is furthermore provided that at least part of the fibers run parallel to the axis of the blank. It is also possible, however, that at least a portion of the fibers have an orientation from 0 to 90°. Particularly when manufacturing elongated components, e.g. in the form of a screw or a strip-shaped mounting part, this results in particular possibilities of adaptation to the necessary strength ranges. The modulus of elasticity of screws manufactured from blanks with fibers aligned axis-parallel is correspondingly higher, in other words such screws tend to be stiffer. It has been shown that the use of [~~axially pressing~~] an extrusion process makes a change in the fiber progression as compared to the fiber progression in the blank possible, so that additional adaptation parameters become possible by means of the special fiber orientation in the blank.

Please amend the first two paragraphs on page 13 as follows:

A variant of the extrusion process as known from metal processing is used to manufacture the corticalis screw (e.g. with a core diameter of 3 mm) from PAEK (polyaryl ethyl ketone) reinforced with carbon fibers. A special variant provides for the use of PEEK (polyether ethyl ketone) reinforced with carbon fibers. The fiber orientation distribution and the mechanical properties of the screw are characterized and brought into relation with the process parameters of the manufacturing process.

The fracture load of the screws manufactured using the extrusion process lies in the range between 3000 and 4000 N, the maximum torsion moment is between 1 and 1.5 Nm, where the maximum angle of distortion according to ISO standard 6475 is up to 370°. The screws possess a modulus of elasticity which decreases from the head towards the tip, and can be designated as being homoelastic with the bone.

Please amend the fourth paragraph on page 14 as follows:

A blank element is heated to the forming temperature (e.g. 350-450 °C) in a heated extrusion die 8 (heating stage), where heating can also take place in consecutive heating

stages 9 and 10 (Fig. 4). The blank 7 is therefore brought into the first heating stage 9, pre-heated accordingly there, heated further in the heating stage 10, and then formed in the negative mold in the region of stage 11. By means of the punch 12, the blank 7 is [~~axially~~] pressed into the negative mold (mold cavity) 13, and receives its final shape there. The pressing speed can be in the range between 2 and 80 mm/s in this connection. The pressing pressure was 120 MPa in various tests. During a subsequent post-pressure stage (pressure approximately 90 MPa), the die is cooled below the glass transition temperature of PAEK (143 °C), using compressed air. After the extrusion die is opened, the finished corticalis screw can be removed. In a subsequent analysis of a screw manufactured in this manner, it was shown that optimum values can be achieved in each instance. This results from the high proportion of fibers, the use of endless fibers, and the very specific forming process for manufacturing the screw. As is evident from Fig. 2, the fibers are aligned predominantly in the direction of the screw axis in the region of the head 2 of the screw 1. In the region of the screw tip, the fibers follow the screw contour (in other words the thread progression) in the edge region, while a

random distribution of the fiber orientation prevails in the core zone.

Please amend the first two paragraphs on page 16 as follows:

Using the example of a corticalis screw, it has been shown that components with complex geometry can also be manufactured by [processing] extrusion of thermoplastic materials reinforced with long fibers, in a hot-forming process. The fiber orientation distribution as the defining variable for the mechanical properties can be controlled, within certain limits, by means of a suitable selection of the fiber orientation in the blank. The other process parameters investigated (forming speed and forming temperature) have a lesser influence on the result.

The tensile strength of [processed] extruded PAEK lies about 30% below that of comparable steel screws, on average. An average fracture strength of 3200 N is sufficient for osteosynthesis applications, since a corresponding screw is already pulled out of the bone at a tensile force of 800-1300 N.

Please amend the last paragraph on page 16 as follows:

With a modulus of elasticity between 5 and 23 GPa, the [processed] extruded corticalis screw is similar to the bone in its elastic behavior. The rigidity in the lengthwise direction clearly decreases towards the tip (decreasing rigidity gradient). In the screwed-in state, the rigid part of the screw (head region) is therefore close to the corticalis and therefore at the most rigid part of the treated bone. With such a rigidity distribution, a force introduction which is extensively adapted to the bone structure can be achieved.

Please amend the paragraph beginning "In the above description ..." on page 17 as follows:

In the above description, the point of departure was an extrusion process which is practically effective only in one direction. In this process, the blank is brought to a corresponding temperature (dough-like or honey-like flowing consistency) and then [~~axially~~] pressed into a negative mold. Within the scope of the invention, it is also possible to use a push-pull extrusion process, specifically for manufacturing strip-shaped, rail-shaped, or plate-shaped parts, but also for screw-like or other connection elements and also for special shapes of parts or for

special structures of bolts, etc. Under some circumstances, a desired fiber orientation and fiber distribution can be achieved by multiple pressing back and forth, in other words by a multiple reversal of the pressing direction. Additional details in this regard will be explained at greater length on the basis of Fig. 6 and 7. The push-pull extrusion process can be of specific importance if, for example, dead-end holes, through openings, indentations, or special shapes are provided in the corresponding part. Then the special progression of the fibers can be influenced, and the component to be manufactured can therefore be particularly reinforced specifically in that region where special reinforcement is necessary.

IN THE CLAIMS

1. **(TWICE AMENDED)** A process for manufacturing components made of fiber-reinforced thermoplastic materials, where a blank [(7)] formed of fibers [(6)] and a thermoplastic material is first pre-finished, and said blank [(7)] is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process, [characterized in that] comprising the steps of:

heating the entire blank [(7) is heated] to a forming temperature in a heating stage, whereby said heated blank assumes a flowing state, [and then axially pressed]

pressing said heated blank into the negative mold [(13), thus giving the blank its shape] and,

shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into the negative mold.

2. **(TWICE AMENDED)** A process for manufacturing components which are under stress, made of fiber-reinforced thermoplastic materials, where a blank [(7)] formed with a fiber proportion of more than 50 volume-% and with at least predominant use of endless fibers and said fiber-reinforced thermoplastic material is first pre-finished, and said blank is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process, [characterized in that] comprising the steps of:

heating the entire blank [(7) is heated] to a forming temperature in a heating stage, whereby said heated blank assumes a flowing state, [and then axially pressed]

pressing said heated blank into the negative mold [(13), thus giving the blank its shape] and,

shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into the negative mold.

3. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein the blank [(7)] is further pre-finished as rod material and is cut to a plurality of lengths required for a final component before the hot-forming process.

4. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] further comprising fibers [(6)] that are endless and have a length that corresponds at least to a length of the blank for a final component [are used].

5. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein said blank [(7)] is composed of layers with different fiber orientation in a lengthwise direction [is formed].

6. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein the blank [(7)] is formed from more than one polymer laminate[, e.g. with several layers with a different matrix material and a different arrangement and/or different volume-% proportion and/or different fiber material and/or different lengths of the fibers].

7. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that a] wherein the shaping of the blank [(7)] is [formed into the final component by means of] accomplished by a push-pull extrusion process.

8. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] further comprising the step of:

heating the blank [(7) is heated] to a forming temperature of 350-450 °C, and then [axially pressed] after pressing said blank into the negative mold [(13), where] and shaping thereby,

cooling said shaped blank below the glass transition temperature of the thermoplastic material [takes place during] in a post-pressure phase.

9. **(TWICE AMENDED)** The process according to Claim 1, [characterized in that during the hot-forming process,] further comprising the step of using carbon or graphite [is used] as a release agent for releasing the shaped blank from the negative mold.

10. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein the blank [(7)] is made of PAEK (polyaryl ether ketones) reinforced with carbon fibers [(6) is processed].

11. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein said blank is formed from endless fibers and at least part of the endless fibers [(6)] run parallel to an axis of the blank [(7)].

12. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein at least a portion of the fibers [(6)] has an orientation from 0 to 90° in the blank [(7)].

13. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein the fibers [(6)] have a length of more than 3 mm.

14. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein the fibers are surrounded by said thermoplastic material, covering a surface of the blank [(7)] during said [giving the blank its final shape] shaping of said blank.

15. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein a pressing temperature and a pressing speed are adjusted as a variable to change position and alignment of the fibers in a finished component.

16. **(THRICE AMENDED)** The process according to Claim 1, [characterized in that] wherein the components receive an additional surface seal during the hot-forming process.